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510(k) Summary

Applicant Information

Applicant Name:	Rotation Medical, Inc.
Applicant Address:	15350 25th Avenue North, Suite 100 Plymouth, MN 55447
Telephone:	763-746-7502
Fax:	763-746-7501
Contact Person:	Jeff Sims Vice President, Clinical Programs and Regulatory Affairs
Date Prepared:	March 19, 2014

Name of Device

Device Common Name:	Tendon Protector
Device Trade Name:	Collagen Tendon Sheet-DDI
Device Classification Name:	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement of Tendon 878.3300 Class II OWY
Secondary Classification Code	ORQ

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s):	Collagen Tendon Sheet-D, K122048 Rotation Medical, Inc.

Description of the Device

Collagen Tendon Sheet-DDI is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet-DDI is designed to provide a layer between the tendon and the surrounding tissue during healing. When hydrated, Collagen Tendon Sheet-DDI is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet-DDI is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, and is packaged preloaded in a cartridge, for use with the Rotation Medical Delivery Instrument, in a dual sterile seal tray-in-tray configuration.

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Intended Use

Collagen Tendon Sheet-DDI is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Summary/Comparison of Technical Characteristics

Collagen Tendon Sheet-DDI is exactly the same product as its predicate, Collagen Tendon Sheet-D (K122048) in regard to all aspects of the collagen scaffold. Only the packaging has changed between the current device and the predicate device. Collagen Tendon Sheet-DDI is packaged in a cartridge to facilitate arthroscopic delivery and positioning of the collagen matrix.

Past safety, biocompatibility and mechanical characterization tests of the predicate product are directly applicable to the current product. Additional tests to confirm the performance characteristics of the packaging change were performed. To confirm performance of the device in the new packaging; suture pull-out testing, hydrothermal transition temperature, and endotoxin testing were evaluated. To confirm the performance of the cartridge assembly itself biocompatibility, simulated use and mechanical integrity tests were evaluated.

In summary, the Collagen Tendon Sheet-DDI device passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices. Testing was conducted in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.

Conclusion

The purpose of this 510(k) application was to notify the Food and Drug Administration of proposed modifications to the packaging of the previously cleared Collagen Tendon Sheet-D (K122048). Collagen Tendon Sheet-DDI and Collagen Tendon Sheet-D are exactly the same device excepting their respective packaging. The proposed packaging modifications for the new device raise no new questions regarding safety and effectiveness. Therefore, the proposed Collagen Tendon Sheet-DDI is substantially equivalent to the predicate Collagen Tendon Sheet-D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Rotation Medical Incorporated
Mr. Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
15350 25th Avenue North, Suite 100
Plymouth, Minnesota 55447

Re: K140300
Trade/Device Name: Collagen Tendon Sheet-DDI
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY, ORQ
Dated: February 3, 2014
Received: February 6, 2014

Dear Mr. Sims:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140300

Device Name
Collagen Tendon Sheet-DDI

Indications for Use *(Describe)*
Collagen Tendon Sheet-DDI is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S
2014.03.25 14:50:46 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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